IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

ANDREW ISOM, individually and, on behalf of those similarly situated,	)	
Plaintiff,	)	
v.	)	**Case No.**
JOHNSON & JOHNSON CONSUMER INC.,	)	
KENVUE, INC.,	)	**JURY TRIAL REQUESTED**
RECKITT BENCKISER LLC,	)	
PROCTER & GAMBLE,	)	
WAL-MART, INC.	)	
WAL-MART STORES EAST 1, LP	)	
Defendants.	)	

COMPLAINT

Plaintiff Andrew Isom, on behalf of himself and all others similarly situated, by and through the undersigned counsel, for his causes of action against Defendants Johnson & Johnson Consumer Inc. ("J&J"), Kenvue, Inc. ("KI"), Reckitt Benckiser LLC ("RB"), Procter & Gamble ("P&G"), Wal-Mart Stores East 1, LP and Wal-Mart, Inc. (collectively "Defendants"), and upon information and belief, states and alleges as follows:

PARTIES

1. Plaintiff Andrew Isom ("Plaintiff"), at all times relevant hereto, was and is a citizen and resident of Missouri who purchased products identified below from Defendants in Missouri and was harmed by Defendants in Missouri.

2. Defendant Johnson & Johnson Consumer Inc. ("J&J"), a McNeil Consumer Healthcare Division, is a New Jersey corporation with its headquarters and principal place of business at 199 Grandview Road, Skillman, New Jersey, 08558. J&J is available for service of process at CSC-Lawyers Incorporating Service Company, 221 Bolivar, Jefferson City, Missouri 65101. J&J manufactures, markets, advertises, labels, distributes, and sells phenylephrine products under its Sudafed and Benadryl product lines.

3. Defendant Kenvue Inc. ("Kenvue") is a Delaware consumer health company, and formerly the consumer healthcare division of Johnson & Johnson. Kenvue is headquartered in Skillman, New Jersey. During the class period defined below, Kenvue acquired McNeil Consumer Healthcare. Kenvue is available for service of process at 199 Grandview Rd., Skillman, New Jersey, 08558, United States.

4. Defendant Procter & Gamble Company ("P&G") is an Ohio corporation with its headquarters and principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. Procter & Gamble is available for service at CT Corporation System, 120 South Central Ave., Clayton, Missouri 63105. P&G manufactures, markets, advertises, labels, distributes, and sells phenylephrine products under its Vicks Nyquil product line.

5. Defendant Reckitt Benckiser LLC ("Reckitt") is a Delaware limited liability corporation with its headquarters and principal place of business located in Parsippany, New Jersey. Reckitt is a wholly owned subsidiary of Reckitt Benckiser Group PLC, a public limited company registered in England and Wales. Reckitt is available for service at CSC-Lawyers Incorporating Service Company, 221 Bolivar, Jefferson City, Missouri 65101. Reckitt manufactures, markets, advertises, labels, distributes, and sells phenylephrine products under its Mucinex product line.

6. Wal-Mart Stores East 1, LP is a Delaware limited partnership with its principal place of business located in Bentonville, Arkansas, and registered to transact business in Missouri. Wal-Mart Stores East 1, LP is available for service at CT Corporation System, 120 South Central Ave., Clayton, Missouri 63105.

7. Wal-Mart, Inc. is a Delaware corporation with its principal place of business located in Bentonville, Arkansas, and registered to transact business in Missouri. Wal-Mart, Inc. is available for service at CT Corporation System, 120 South Central Ave., Clayton, Missouri 63105. Wal-Mart Stores East 1, LP and Wal-Mart, Inc. are hereinafter sometimes collectively referred to as "Wal-Mart." Wal-Mart markets, advertises, labels, distributes, and sells phenylephrine products under its Equate product line.

8. Defendants J&J, Kenvue, P&G, Reckitt and Wal-Mart are hereinafter sometimes collectively referred to as "Defendants."

JURISDICTION AND VENUE

9. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which there are in excess of 100 class members. Plaintiff is a citizen of a state different from Defendants.

10. This Court has jurisdiction over each Defendant because all Defendants are authorized to conduct business in Missouri and/or within the long-arm jurisdiction of the Court because Defendants have marketed, promoted, distributed, and sold the Products in Missouri. Defendants knew and understood that the Products would be marketed, distributed and advertised to consumers in Missouri. Accordingly, this Court may exercise jurisdiction over Defendants because Defendants have sufficient minimum contacts with this State and/or sufficiently availed

themselves of the markets in this State through promotion, sales, distribution and marketing the Products within this State.

11. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendants transact substantial business in this District.

FACTUAL ALLEGATIONS RELEVANT TO ALL COUNTS

Introduction

12. This is a class action lawsuit brought on behalf of consumers who purchased Defendants' over-the counter ("OTC") decongestant products containing phenylephrine (i.e., the "Products").

13. Within the Class Period defined below, Plaintiff purchased in Missouri the following products for personal and household use to relieve congestion associated with a cold: Sudafed PE, Vick's DayQuil Vick's Nyquil Cold & Flu, Vicks Nyquil Severe Cold & Flu, Vicks Nyquil Cold + Flu plus Congestion, Mucinex Sinus Max, and Wal-Mart Equate Products.

14. During the Class Period, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' oral decongestant Products were not an effective remedy for congestion and/or cold symptoms. None of these products was effective in relieving congestion.

15. Plaintiff purchased Defendants' Products on the assumption that the labeling of the Products was accurate and that the Products worked as advertised. Plaintiff would not have purchased Defendants' Products had he known they were not effective and lacked the ability to provide relief for congestion and/or cold symptoms as marketed by Defendants. As a result,

Plaintiff suffered injury in fact when he spent money to purchase Products he would not otherwise have purchased absent Defendants' misconduct, as alleged herein.

16. Plaintiff continues to be exposed to Defendants' marketing materials for these ineffective Products. Plaintiff continues to encounter the Products on display for sale to consumers at retail businesses where he regularly shops. Plaintiff would purchase Defendants' Products again in the future if he were assured that Defendants' Products had been reformulated using GRASE ingredients that are proven effective for decongestant relief as advertised by Defendants.

The Products

17. The Products are manufactured, sold, and distributed by Defendants and have been found by the U.S. Food and Drug Administration ("FDA") to lack efficacy.

18. Defendants have long been aware of the lack of efficacy but have continued to sell the Products.

19. The Products' lack of efficacy was not disclosed to Plaintiff prior to Plaintiff's purchase of the Products. Plaintiff would not have purchased the Products had he known they did not work as advertised. Plaintiff and the putative class suffered economic damages due to Defendants' misconduct (as set forth below). They seek injunctive relief and restitution for the full purchase price of the Products they purchased.

20. Defendants marketed and sold the Products to consumers in Missouri including to Plaintiff Andrew Isom, and across the United States as an effective nasal decongestant.

21. The primary "active ingredient" in the Products is phenylephrine hydrochloride ("PE" or "phenylephrine"). However, "[n]o support has been found in the literature in the public domain for the efficacy of PE as a nasal decongestant when administered orally."[1]

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000711/ (last viewed Sept. 21, 2023).

22. Sales of the Products are substantial, more than 242 million packages or bottles of phenylephrine products were sold in 2022, resulting in $1.76 billion in sales.

23. The FDA has previously designated PE as generally recognized as safe and effective ("GRASE"), despite the lack of peer-reviewed scientific evidence to support PE's efficacy as an oral decongestant. However, after a two-day meeting on September 11-12, 2023, the FDA concluded that the scientific data do not support a GRASE designation for PE as an ingredient in cough and cold OTC medications.

24. An FDA GRASE designation permits pharmaceutical products companies (like Defendants) to market products (like Sudafed PE, Vicks NyQuil, Mucinex and Equate) that contain GRASE ingredients directly to consumers as OTC medications.

25. OTC medicines do not require a prescription and are typically freely available from many kinds of retailers. In the United States alone, "there are more than 750,000 retail outlets that sell OTC products."[2]

26. In 2022, PE versions of oral cough and cold decongestant OTC medications accounted for about 80% of "the $2.2 billion market," while PDE versions made up the other 20%.[3]

Defendants' Marketing and Sales Practices

27. For years, Defendants have advertised, and continue to advertise, PE as an effective decongestant that relieves nasal congestion and sinus pressure associated with colds, allergies, and other respiratory conditions, even though Defendants knew or should have known that the current scientific data demonstrate that oral PE is ineffective as a nasal decongestant.

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[2] https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics (last visited Sept. 21, 2023).

[3] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say#:~:text=WASHINGTON%20(AP)%20%E2%80%94%20The%20leading,the%20long%2Dquestioned%20drug%20ingredient (last viewed Sept. 21, 2023).

28. As a result of its aggressive and misleading marketing tactics, Defendants' Products "generated nearly $1.8 billion in sales last year alone."[4]

29. According to Defendants, phenylephrine works by constricting blood vessels in the nasal passages, which reduces swelling and congestion. Over the many years preceding the filing of this Complaint, Defendants have made extensive claims in their marketing materials concerning the efficacy of their Products.

30. For Sudafed PE Products, these claims include:

a. Relief from Nasal Congestion: Sudafed PE products provide relief from nasal congestion associated with colds, allergies, or sinus congestion.

b. Fast-Acting: Some Sudafed PE products are fast-acting and provide rapid relief from congestion symptoms.

c. 24-Hour Relief: Sudafed PE provides up to 24 hours of relief from congestion symptoms, reducing the need for frequent dosing.

d. Sinus Pressure Relief: Sudafed PE is highly effective in relieving sinus pressure in addition to congestion.

e. Sudafed PE offers relief from multiple cold and allergy symptoms, such as nasal congestion, sinus pressure, sneezing, and runny nose.

31. For Vicks Nyquil Products, these claims include:

a. fast, powerful, maximum strength 9-symptom relief to treat… stuffy nose…sinus congestion.

b. Proven relief for your worst cold and flu symptoms.

c. Effective cold and flu symptom relief.

d. The congestion, pressure & pain, clear your head, medicine.

e. Fast Relief- Clear your head with fast acting nighttime relief.

f. Powerful congestion, pressure and pain relief.

[4] https://www.cnn.com/2023/09/12/health/phenylephrine-tablets-ineffective-fda-panel-says/index.html (last viewed Sept. 21, 2023).

g. Maximum strength sinus relief.

h. Fast, powerful cold and congestion relief.

32. For Mucinex Products, these claims include:

a. Clears sinus congestion.

b. Relieve sinus pressure.

c. Starts to break up Sinus Symptoms with Just 1 Dose.

d. 3 maximum strength medicines help thin and loosen mucus, clear nasal passages and sinus congestion.

33. For Equate Products, these claims include:

a. Relief for nasal and sinus congestion.

b. Powerful relief for sinus pressure due to the common cold.

c. Fast, maximum strength relief from your sinus pressure.

PE's GRASE Designation

34. The FDA "first approved phenylephrine as a safe and effective [OTC] decongestant in the 1970s."[5] In 1994, the FDA issued a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective ("GRASE") and not misbranded. Phenylephrine is included in the final monograph as an OTC oral nasal decongestant.[6]

35. In or around 2007, "researchers at the University of Florida petitioned the government to examine" the use of phenylephrine in popular OTC cold medications, "arguing that there is little evidence the reformulated products [containing PE instead of PDE] work in adults or

[5] https://www.cato.org/blog/after-50-years-fda-finds-out-oral-phenylephrine-doesnt-work#:~:text=The%20FDA%20first%20approved%20phenylephrine (last viewed Sept. 21, 2023).
[6] Phenylephrine "was approved by the FDA based on in-house studies provided by pharmaceutical companies, not as a result of clinical trials." https://www.drugs.com/medical-answers/differencebetween-phenylephrine-pe-3509033/ (last viewed Sept. 21, 2023).

are safe in children."[7] In response, the FDA held a meeting where it "ask[ed] a panel of outside experts whether new formulations of Sudafed and other [OTC] cold medications actually relieve nasal congestion."[8]

36. At this 2007 meeting, the "advisory panel told the FDA that evidence oral phenylephrine worked was 'murky' and 'not definitive' and recommended further study."[9] Nevertheless, upon the conclusion of the 2007 meeting, the FDA determined phenylephrine to be GRASE, but with a clear caveat—specifically, the "FDA allowed the [OTC phenylephrine-containing] products to remain on the market *pending additional research*."[10] To reiterate, PE "was approved by the FDA based not on results from clinical trials, but studies conducted by pharmaceutical companies themselves."[11]

The FDA's Nonprescription Drug Advisory Committee

37. In 2023, the FDA's Nonprescription Drug Advisory Committee ("NDAC") issued a new report detailing the efficacy (or, rather, lack thereof) of oral PE "as an active ingredient in [OTC] cough and cold products."[12]

38. During the NDAC's two-day meeting on September 11th and 12th, 2023, it revisited studies it initially reviewed in 2007, and considered additional studies obtained since that time. This two-day meeting was "prompted by" the "same [University of Florida] researchers who

[7] https://www.nbcnews.com/health/health-news/fda-panel-study-reformulated-cold-medsflna1c9464568 (last viewed Sept. 21, 2023).
[8] *Id.*
[9] https://www.cato.org/blog/after-50-years-fda-finds-out-oral-phenylephrine-doesnt-work#:~:text=The%20FDA%20first%20approved%20phenylephrine (last viewed Sept. 21, 2023).
[10] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say (last viewed Sept. 21, 2023) (emphasis added).
[11] https://www.usatoday.com/story/news/health/2023/09/12/fda-panel-declares-decongestantphenylephrine-ineffective/70835249007/ (last viewed Sept. 21, 2023).
[12] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine (last viewed Sept. 21, 2023).

challenged [PE's] effectiveness in 2007."[13] These researchers again "petitioned the FDA to remove most [PE] products based on recent studies showing [PE products] failed to outperform placebo pills in patients with cold and allergy congestion."[14]

39. Based upon its review of past and new data, the NDAC *unanimously* concluded that the "scientific data do not support [its previous conclusion, based on data supplied by pharmaceutical companies] that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant."[15] The NDAC of the FDA highlighted fatal flaws in the studies it previously relied upon in 2007, explaining that, "all of the studies (both positive and negative) were highly problematic in both design and methodology." The NDAC also mentioned a 2017-2018 study conducted by Defendant J&J that suggested that oral PE products have "no beneficial effect when compared with [a] placebo."

40. For these and other reasons, the NDAC unanimously declared on September 12, 2023, that phenylephrine, the active ingredient in the Products, is an ineffective decongestant.

41. The NDAC's 2023 report is supported by large clinical trials disproving PE's efficacy. Those studies provide evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg. The results of several studies, reported after 2007, clearly demonstrate that PE is no more effective than placebo in decreasing nasal congestion and, thus, lacks efficacy.

Defendants' Knowledge

42. As of 2007, nasal airway resistance ("NAR") was the principal methodology used to assess the effectiveness of oral PE. This methodology used measurements of airflow and air

[13] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say (last viewed Sept. 21, 2023).
[14] *Id.*
[15] *Id.*

pressure in the nasal passage to calculate NAR as an indirect measure of the level of nasal congestion.

43. However, in 2018, the FDA issued new guidance for industry as it related to the use of nasal congestion symptom scores to evaluate congestion, meaning that NAR was no longer used as a primary endpoint to evaluate congestion in studies.

44. Based on the FDA's new 2018 guidance, Defendants knew or should have known that their marketing claims regarding the Products' efficacy were false and misleading. This is because the primary endpoint for evaluating the efficacy of the Products had changed since the FDA's 2007 NDAC meeting, meaning that the previous data under which the Products were approved as GRASE no longer supported efficacy.

45. Additionally, Defendants—as manufacturers of OTC PE-based Products—knew or should have known that there have been no published studies since the FDA's revised 2008 guidance for the industry released which demonstrate the effectiveness of oral PE as a decongestant. Rather, the body of scientific literature has consistently shown oral PE to be clinically ineffective.

46. Accordingly, Defendants knew or should have known by at least 2018 that their marketing claims regarding the Products' efficacy were false and misleading. Additionally, consumers routinely reported that such products lacked efficacy via consumer complaints submitted, *inter alia,* on the Defendants' own websites.

47. Plaintiff and the class members purchased the Products in reliance on Defendants' false and deceptive marketing claims.

48. As a result of Defendants' false and deceptive marketing, Plaintiff and the class members suffered economic damages, including the cost of purchasing the Products.

Tolling

49. Plaintiff did not discover and could not have discovered through the exercise of reasonable diligence, the existence of the claims sued upon herein until immediately prior to commencing this civil action.

50. Any applicable statutes of limitation have been tolled by Defendants' affirmative acts of fraudulent concealment and continuing misrepresentations, as the facts alleged above reveal.

51. Because of the self-concealing nature of Defendants' actions and their affirmative acts of concealment, Plaintiff and the Classes assert the tolling of any applicable statutes of limitations affecting the claims raised herein.

52. Defendants continue to engage in the deceptive practice, and consequently, unwary consumers are injured on a daily basis by Defendants' unlawful conduct. Therefore, Plaintiff and the Classes submit that each instance that Defendants engaged in the conduct complained of herein and each instance that a member of any Class purchased Defendants' Product constitutes part of a continuing violation and operates to toll the statutes of limitation in this action.

53. Defendants are estopped from relying on any statute of limitations defense because of their unfair or deceptive conduct.

54. Defendants' conduct was and is, by its nature, self-concealing. Still, Defendants, through a series of affirmative acts or omissions, suppressed the dissemination of truthful information regarding their illegal conduct, and actively have foreclosed Plaintiff and the Classes from learning of their illegal, unfair, and/or deceptive acts.

55. By reason of the foregoing, the claims of Plaintiff and the Classes are timely under any applicable statute of limitations, pursuant to the discovery rule, the equitable tolling doctrine, and fraudulent concealment.

CLASS ALLEGATIONS

56. Plaintiff brings this action on behalf of himself and all other similarly situated class members (the "Class" or "Classes") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following classes and subclasses against Defendants:

a. All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Johnson & Johnson in the United States (the "Johnson & Johnson Nationwide Class");

b. All persons in the State of Missouri who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Johnson & Johnson (the "Johnson & Johnson Missouri Subclass");

c. All persons in the State of Kansas who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Johnson & Johnson (the "Johnson & Johnson Kansas Subclass");

d. All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Reckitt Benckiser in the United States (the "Reckitt Nationwide Class").

e. All persons in the State of Missouri who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Reckitt Benckiser (the "Reckitt Missouri Subclass").

f. All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Kenvue in the United States (the "Kenvue Nationwide Class").

g. All persons in the State of Missouri who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Kenvue (the "Kenvue Missouri Subclass").

h. All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Procter& Gamble in the United States (the "Procter & Gamble Nationwide Class").

i. All persons in the State of Missouri who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Procter& Gamble (the "Procter & Gamble Missouri Subclass").

j. All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Wal-Mart in the United States (the "Wal-Mart Nationwide Class").

k. All persons in the State of Missouri who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Wal-Mart (the "Wal-Mart Missouri Subclass").

57. Plaintiff reserves the right to amend the class definitions as appropriate, as the case proceeds.

58. The members of the classes are so numerous that joinder of all members of the classes is impracticable. Plaintiff is informed and believes that the proposed class/sub-classes contain thousands of purchasers of Defendants' Products who have been damaged by Defendants' conduct as alleged herein. The precise number of class members is unknown to Plaintiff at this time.

59. Plaintiff's claims are typical to those of all class members because members of the classes are similarly injured through Defendants' uniform misconduct described above and were subject to Defendants' deceptive marketing claims that accompanied each and every Product. Plaintiff is advancing the same claims and legal theories on behalf of all members of the classes and sub-classes.

60. Plaintiff's claims raise questions of law and fact common to all members of the classes, and they predominate over any questions affecting only individual class members. The claims of Plaintiff and all prospective class members involve the same alleged defect. These common legal and factual questions include the following:

a. whether Defendants' Products contained phenylephrine;

b. whether Defendants' marketing statements are false, misleading, or objectively reasonably likely to deceive;

c. whether the alleged conduct constitutes violations of the laws asserted;

d. whether Defendants' alleged conduct violates public policy;

e. whether Defendants engaged in false or misleading advertising;

f. whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising and/or selling of the Products;

g. whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and

h. whether an injunction is necessary to prevent Defendants from continuing to market and sell Products that lack efficacy.

61. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and have the resources and abilities to fully litigate and protect the interests of the class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

62. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

63. The class also may be certified because Defendants have acted or refused to act on grounds applicable to the class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the class as a whole.

64. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire class, on grounds generally applicable to the entire class, to enjoin and prevent defendant from engaging in the acts described above, such as continuing to market and sell Products that lack efficacy and requiring Defendants to provide a full refund of the purchase price of the Products to Plaintiff and class members.

65. Unless a class is certified, Defendants will retain monies received as a result of their conduct that were taken from Plaintiff and the class members. Unless a class-wide injunction is issued, Defendants will continue to commit the violations alleged and the members of the class and the general public will continue to be misled. Indeed, to this day, Defendants continue to market and sell the Products that have been determined by a unanimous FDA NDAC to lack efficacy.

COUNT I - Violation of the Missouri Merchandising Practices Act

66. Plaintiff incorporates herein by reference the allegations set forth above as though fully set forth in this Count I.

67. Plaintiff brings this Count I on behalf of the Missouri subclasses against all Defendants.

68. The acts and practices engaged in by Defendants, and described herein, constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, R.S.Mo. § 407.010, *et seq.*

69. Defendant engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in

connection with the sale, distribution or advertisement of the Products, in violation of R.S.Mo. § 407.020.

70. Plaintiff and the putative class members purchased the Products, a product that was falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act, and as a result, Plaintiff and the putative class members suffered economic damages in that the product purchased was worth less than the product they thought they had purchased had Defendants' representations been true.

COUNT II – Unjust Enrichment

71. Plaintiff incorporates herein by reference the allegations set forth above as though fully set forth in this Count II.

72. Plaintiff brings this Count II on behalf of the nationwide classes against all Defendants.

73. Plaintiff and the putative class members conferred a benefit upon the Defendants by purchasing the Products.

74. Defendants appreciated and had knowledge of the benefit conferred upon them as referenced above.

75. Defendants accepted and retained the benefit conferred upon them by Plaintiff and the putative class members under such circumstances that acceptance and retention of the benefit is not equitable without payment for the same to the Plaintiff and class.

76. As a direct and proximate result of the Defendants' actions set forth above, the Plaintiffs and the class members have suffered pecuniary damages resulting from the purchase of the Products in an amount that has not yet been determined.

COUNT III—Breach of Implied Warranty

77. Plaintiff incorporates herein by reference the allegations set forth above as though fully set forth in this Count III.

78. Plaintiff brings this Count III on behalf of the nationwide classes against all Defendants.

79. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose.[16]

80. Defendants were at all times a "merchant" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

81. The Products are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

82. Defendants were obligated to provide Plaintiff and the other class members Products that were of merchantable quality, were reasonably fit for the purpose for which they were sold and conformed to the standards of the trade.

83. Defendants impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

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[16] *See e.g.*, Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75- 2-314; Mo. Rev. Stat. § 400.2- 314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382- A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2- 314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36- 2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2- 314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

84. Defendants breached their implied warranties, because their Products were not of merchantable quality or fit for their ordinary purpose.

85. Defendants' breaches of implied warranties were a direct and proximate cause of Plaintiff's and the other class members' damages.

COUNT IV—Fraud by Omission/Concealment

86. Plaintiff incorporates herein by reference the allegations set forth above as though fully set forth in this Count IV.

87. Plaintiff brings this Count IV on behalf of the nationwide classes against all Defendants.

88. Defendants intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality or grade of the Products.

89. Due to Defendants' fraudulent conduct, Plaintiffs and the other class members have suffered actual damages.

90. Defendants knew that phenylephrine is ineffective at safe dosages when consumed orally.

91. Defendants were obligated to inform Plaintiff and the other members of the class of the effectiveness of phenylephrine due to their exclusive and superior knowledge of the Products.

92. Plaintiffs and other class members also expressly reposed a trust and confidence in Defendants because the nature of their dealings as a healthcare entity and with Plaintiffs and other members of the class as their consumers.

93. Plaintiffs and the other class members would not have purchased the Products but for Defendants' omissions and concealment of material facts regarding the nature and quality of the Products and existence of the Products, or would have paid less for the Products.

94. Defendants knew their concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

95. Defendants acted with malice, oppression, and fraud.

96. Plaintiffs and the other class members reasonably relied on Defendants' knowing, affirmative, and active false concealment and omissions. As a direct and proximate result of Defendants' omissions and active concealment of material facts regarding the Products, Plaintiffs and the other class members have suffered actual damages in an amount to be determined at trial.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues stated herein, and all issues so triable.

Dated: October 13, 2023

Respectfully submitted,

THE A.W. SMITH LAW FIRM, P.C.

/s/ AW Smith

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